



Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL
Testosterone Gel 1%, 2.5 grams, CIII
November 07, 2025

Testosterone Gel 1%, 2.5 grams, CIII, for topical use				
Carton NDC	Packet NDC	Lot #	Exp. Date	Size
0591-3216-30	0591-3216-17	100068692	04/2027	30 packets/carton

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary nationwide recall of the above one (1) lot of **Testosterone Gel 1%, 2.5 grams, CIII, for topical use**, to the **RETAIL LEVEL**. The product in this recall is distributed under the Actavis Pharma Inc. label. The reason for the recall is that a defect in the side-seal was discovered in packets of Testosterone Gel 1% from lot # 100068692, making it possible for the gel product to leak from the packets. The primary health concern associated with this defect is a potential reduction in treatment efficacy due to underdosing of testosterone. This may lead to insufficient control of testosterone deficiency disorders, resulting in inadequate management of the underlying condition (deficiency or absence of endogenous testosterone). Teva's health hazard assessment concluded that exposure to the product of concern could lead to mild adverse events, and the likelihood of harm occurrence is possible. Consequently, the overall risk of harm in the patient population is considered to be low.

This recall is being made with the knowledge of the Food and Drug Administration.

Please take the following actions upon receipt of this letter:

- Immediately examine your inventory for Testosterone Gel 1%, 2.5 grams, CIII, for topical use, lot # 100068692.
- Immediately discontinue distribution of and quarantine Testosterone Gel 1%, 2.5 grams, CIII, for topical use, lot # 100068692.
- TEVA's records indicate that the recalled lot # 100068692 was commercially distributed/shipped to its direct customers from 06/10/2025 through 09/26/2025.
- **If you have further distributed Testosterone Gel 1%, 2.5 grams, CIII, for topical use, lot # 100068692, please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Business Reply Form (BRF) as a basis for your recall notification.**

Promptly complete the attached Recall BRF, even if you have no product to return, and return the completed Recall BRF in its entirety to Inmar, Attention: Recall Coordinator, by any one of these means:

MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101
EMAIL: rxrecalls@inmar.com
FAX: 817-868-5362

Please note: the Recall BRF must be filled out. If the Recall BRF form is not filled out correctly and, in its entirety, no credit will be issued.

After receipt of your Recall BRF, Inmar will send labels for your Return Goods Authorization (RGA) and shipping of your product return. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
<p>Product Returns: Contact Inmar at 877-268-8228 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from: clsnetlink.com</p>
<p>Medical-related Questions or to report an Adverse Event: Contact Teva Medical Information at: 888-838-2872, option 3, then option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at druginfo@tevapharm.com</p>
<p>Product Quality Complaint-related Questions: Contact Teva Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at QAS.QAS@tevapharm.com</p>
<p>Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3, then option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week</p>
<p>FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088</p>

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.



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RECALL BUSINESS REPLY FORM

Date Form Completed _____

This form must be filled out completely. If this form is not filled out correctly and, in its entirety, no credit will be issued. Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 EMAIL: rxrecalls@inmar.com FAX: 817-868-5362

Section 1 - Customer Information

This Stock Response is for (Check One):

[] Teva Direct Account [] Non-Direct Customer

Customer/Store Name: Address (Street/City/State/Zip):
*DEA #: *Debit Memo #:
*DEA # is required in order to process your form. *Debit Memo # is required in order to process your form.
Contact Name (please print): Telephone #:

Please mark your answer - I have checked my stock and:

[] I do have stock of the recalled item(s) (complete section 2) OR [] I do not have stock of the recalled item(s).

Teva Direct Accounts

Does your response include all your DC locations? [] YES [] NO
Did you communicate the recalls to your direct accounts [] YES [] NO

Non-Direct Customer

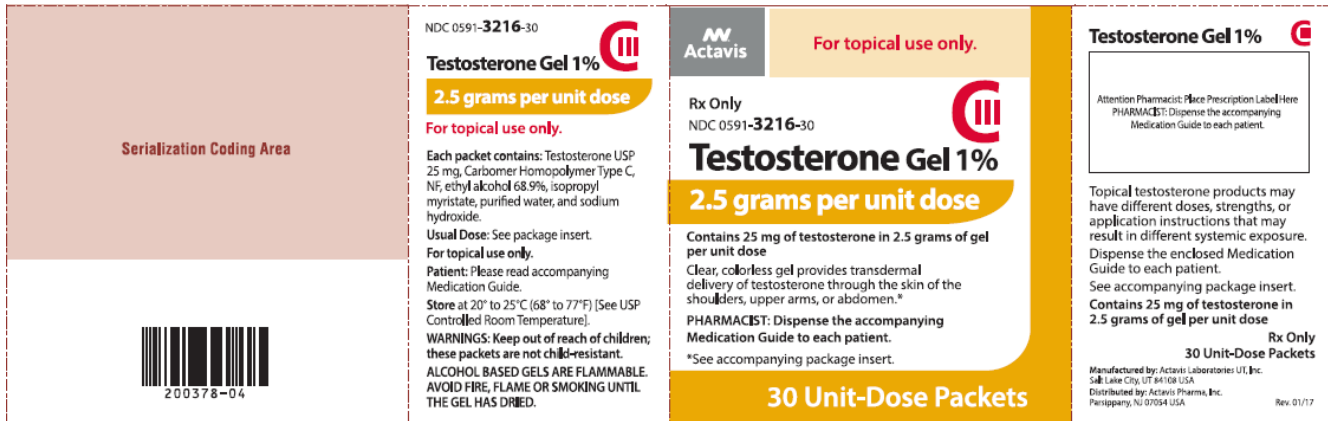
The product(s) in this recall were purchased from: _____
Name of Your Wholesaler/Distributor and Location

Section 2 - Quantity of Product to Return

Enter the information of the recalled product(s) to be returned in the table below. If additional space is needed, please make copies of this form.

Table with 5 columns: Carton NDC #, Packet NDC #, Size, Lot #, # of Cartons to Return (Count Partial as 1)

Image Shown Has Not Been Reproduced to Scale of Actual Label



Please indicate the number of shipping labels that you need to return the recalled product(s): _____

Inmar/MedTurn Use Only:
Scan Labels Store Kit D.B